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Guidance for the Reregistration of Pesticide Products Containing Metaldehyde as the Active Ingredient

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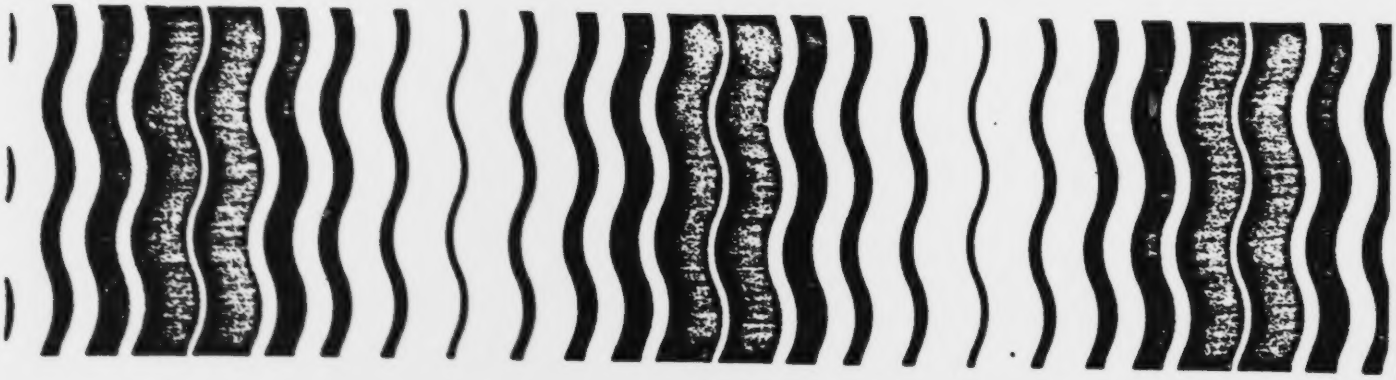
Guidance for the Reregistration of Pesticide Products Containing METALDEHYDE as the Active Ingredient



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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
METALDEHYDE
AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 9002-91-9 (HOMOPOLYMER)
108-62-3 (TETRAMER)

OPP Chemical Code 053001

EPA CASE NUMBER 0576

December 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, DC 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product

NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per million
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,[1] focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, D.C. 20460

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

Common Name: Metaldehyde

Chemical Name: 2,4,6,8-tetramethyl-1,3,5,7-tetraoxycyclo-octane

Chemical Family: Hydrocarbon

Trade Names: Meta, Metason, Halizan, Antimilace, Namekil, Cekumeta

CAS Registry No.: 9002-91-9 (homopolymer)
108-62-3 (tetramer)

OPP Chemical Code: 053001

Empirical Formula: $C_8H_{16}O_4$

Molecular Weight: 176.2

Chemical/Physical Characteristics:

Color: White
Physical State: Crystalline powder
Odor: Aldehyde odor
Melting Point: 246° C
Bulk Density: 65g/100cc
Solubility: at 20° C, 0.2 g/L in water and very slightly soluble in alcohol
Vapor Pressure: 1mm Hg at 20° C
Flammability: 36-40° C

B. USE PROFILE

Type of Pesticide: Molluscicide

Year of Initial Registration: 1962

Registered Uses:

TERRESTRIAL FOOD CROP: alfalfa, almond, anise, apple, apricot, artichoke, asparagus, avocado, banana, barley, beans, beets, blackberry, blackeyed peas, blueberry, boysenberry, broccoli, brussels sprouts, cabbage, caneberry, cantaloupes, caraway, carrots, catnip, cauliflower, celery, cereal crops, cherry, chicory, chive, citrus fruits, clover, cole crops, collards, coriander, corn, cowpeas, cucumber, currant, dewberry, dill, eggplant, endive, garlic, ginseng, gooseberry, grapefruit, grapes, horseradish, kale, kohlrabi, leek, legume, lemon, lentils, lettuce, lime, loganberry, melons, muskmelons, mustard, mustard greens, nectarine, oats, okra, onion, orange, oregano, parsley, parsnip, peach, pear, peas, pecan, peppermint, peppers, pimento, plum, potato, pumpkin, radish, raspberry, rhubarb, rutabaga, sage, salsify, savory, shallot, spearmint, spinach, squash, stone fruits, strawberry, sugar beets, sweet potato, swiss chard, thyme, tomato, turnips vegetable crops, walnut, watermelons, wheat; seed crops: alfalfa, beans, clover, corn (sweet), grasses, peas, potato.

TERRESTRIAL NONFOOD CROP: seed crops: beets, cabbage, carrots, collards, kale, kohlrabi, lettuce, mustard, radish, spinach, swiss chard, tobacco, turnips.

GREENHOUSE FOOD CROP: asparagus, beans, beets, cabbage, carrots, celery, corn, cucumber, eggplant, endive, lettuce, melons, onion, peas, peppers, potato, radish, spinach, squash, tomato, turnips.

GREENHOUSE NONFOOD CROP: orchids, ornamental plants.

DOMESTIC AND NONDOMESTIC OUTDOOR: domestic dwellings, greenhouses, lath houses, lawns (including dichondra), ornamental grasses, ornamental plants (including nursery stocks), turf.

INDOOR: farm buildings.

Pests Controlled: slugs and snails

Methods of Application: by hand, ground, or aerial equipment

Formulations: wettable powders, dusts, emulsifiable concentrates, flowable concentrates, granules, ready-to-use products (liquids) and pelleted/tableted

Annual Usage: 400,000 - 600,000 lbs ai (1986 estimate)

Predominate Usage: home orchards, gardens and ornamentals, and commercial vegetables (artichokes, broccoli, cauliflower, lettuce, cabbage, and tomatoes), and fruits (citrus, stone, pome, and strawberries)

U. S. Producer: Lonza, Incorporated

Number of Registrations: 77 end-use products (EPs), 4 technical products/formulation intermediates, and 7 "special local need" registrations

C. BACKGROUND

Historically, the Agency did not consider the use of baits in-field to protect fruits and vegetables to be a food use and tolerances were not required. However, Residue Chemistry Guidelines, updated in October 1982, state that if residues could occur in foods or feed, the use is considered to be a food use and a petition for tolerance/exemption from tolerance is required. The Agency has no basis for concluding that residues will not occur in the food and feed crops treated with metaldehyde. Therefore, EPA will require data on metaldehyde to support food uses.

III. AGENCY ASSESSMENT

The Agency has reviewed all data currently supporting the registration of metaldehyde as of April 1988. Based on the available data, EPA has reached the following conclusions.

A. HEALTH EFFECTS ASSESSMENT

Toxicology. Metaldehyde is of moderate to low acute toxicity by the oral route and of low acute toxicity by dermal and inhalation exposure. Metaldehyde was not found to be a dermal irritant. However, all of the available acute studies must have the purity of the test material established before they can be fully accepted.

The only other available data are a partially acceptable mutagenicity study and a nonrodent subchronic study which provides supplementary information but is not acceptable for fulfilling data requirements.

In the chromosome aberration assay, the portion performed in the absence of metabolic activation system is acceptable; metaldehyde was not found to be clastogenic under the conditions of the assay.

In a 26-week dog feeding study with metaldehyde, the possibility of degenerative changes in the liver, prostate, and male gonads was suggested. Because of certain deficiencies in its conduct, this study is not acceptable for fulfilling registration requirements.

The remainder of the toxicity data base is essentially either inadequate or vacant because of past policy classifying bait formulations as nonfood uses. Data are required as set forth in Table A of this document.

Poisoning Incidents. Poisoning incident reports show that the use of metaldehyde, especially homeowner use, has been associated with dog poisonings. These reports indicate that dogs have died as a result of metaldehyde poisonings. There are also numerous reports of children ingesting metaldehyde baits, but no adverse effects have been reported.

Worker Exposure/Reentry. Because of the low acute toxicity of metaldehyde, mixer/loaders and applicators are not expected to experience adverse effects as a result of their exposure to metaldehyde. The Agency has determined that, because of the low acute toxicity of metaldehyde and the use patterns of this pesticide, reentry data are not required.

B. ENVIRONMENTAL PROFILE

Ecological Effects. None of the available ecological effects data meet Agency requirements. However, the available data suggest that metaldehyde is of low toxicity to birds and is practically nontoxic to aquatic organisms. Data are required as set forth in Table A.

Based on the nature of registered metaldehyde formulations and uses, significant bee exposure is not anticipated. Thus, bee data are not required for metaldehyde.

Environmental Fate. Presently, the Agency does not have adequate environmental fate data on which to base environmental fate and groundwater leaching assessments for metaldehyde. Metaldehyde is a polymer of acetaldehyde and its initial breakdown product is expected to be acetaldehyde. Data are required as set forth in Table A.

C. TOLERANCE REASSESSMENT

Tolerances Issued. Although tolerances had not been generally required for food/feed uses of baits, there is a food additive regulation of zero ppm for strawberries (40 CFR 185.4025). This is not supported by adequate data. A tolerance assessment will be made when the essential toxicity and residue data are available. The tolerance is expressed in terms of metaldehyde *per se*.

EPA has evaluated the residue and toxicology data pertaining to metaldehyde. The results of the Agency's evaluation are as follows:

Residue Data. No acceptable data are available on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of the pesticide. Data are required as set forth in Table A.

No acceptable analytical methodology for determining the levels of residues in plants and animals are available. Data are required as set forth in Table A.

The submitted data do not establish appropriate storage conditions. Data are required as set forth in Table A.

Data on the magnitude and levels of residues of metaldehyde in individual raw agricultural commodities, animal products, and processed food and feed items are either inadequate or completely lacking. Data are required as set forth in Table A.

The Food and Drug Administration (FDA) Total Diet Studies, as well as Surveillance and Compliance program for domestic and imported commodities do not employ methodology capable of determining residues of metaldehyde.

No Codex MRLs or Canadian or Mexican tolerances have been established in or on food or feed commodities or in animal products.

Toxicology. The toxicological data are inadequate to allow an assessment of any dietary exposure to metaldehyde.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on metaldehyde, the Agency has made the following determinations:

1. Metaldehyde is not being placed into Special Review at this time.

Rationale: Since there are so few acceptable studies available to support registration of products containing metaldehyde, the Agency is not able to determine whether any of the criteria of 40 CFR 154.7 have been met or exceeded.

2. The Agency is not restricting the use of metaldehyde at this time.

Rationale: FIFRA section 3(d)(1)(C) provides that some or all uses of a pesticide will be classified for restricted use if the Administrator determines that without such restriction the pesticide "may generally cause unreasonable adverse effects in man or the environment." The Agency does not have sufficient data at this time to determine if metaldehyde meets any of the risk criteria of 40 CFR 152.170. Upon receipt of data required under this Standard, the Agency will apply the criteria of 40 CFR 152.170 to determine if any uses of metaldehyde warrant restricted use classification.

3. The Agency will continue to require precautionary statements to protect dogs and other pets, but special precautionary statements for children are not necessary.

Rationale: Poisoning incident reports continually indicate fatalities to dogs associated with the use of metaldehyde baits but there is no evidence that exposed children have been adversely affected.

4. The Agency will assess metaldehyde's potential for contaminating ground water upon receipt of the required environmental fate data set forth in Table A of this Standard.

Rationale: The Agency is unable to assess the potential for metaldehyde to contaminate ground water because the environmental fate of this chemical is uncharacterized. When data required in this Standard have been received and evaluated, the Agency will assess metaldehyde's potential for ground water contamination.

5. The Agency is classifying in-field uses of metaldehyde on food and feed crops as food uses and is requiring tolerances/exemptions from tolerances. Tolerances supported by

data must be proposed for residues of metaldehyde in or on any agricultural commodities on which metaldehyde is used. When a strawberry tolerance is established, the existing food additive regulation for strawberries will be revoked. Additionally, tolerances must be proposed, and supporting residue data provided, for the forage and fodder of field corn, popcorn and sweet corn, for the forage hay, and straw of wheat (which will be translated to barley and oat straw) and for spent mint hay. Alternatively for these latter commodities, the registrant may propose a feeding restriction for such commodities as appropriate.

Rationale: Historically, the use of baits in-field to protect fruits and vegetables was not considered to be a food use and tolerances were not required. Current Residue Chemistry Guidelines (October 1982;34) state that "... if residues could occur in foods or feed, then the use is a food use and a petition for tolerance/exemption from tolerance is required." The Agency has no basis for concluding that residues will not occur in the food and feed crops listed. Therefore, these uses are now considered to be food uses.

6. The Agency will not approve tolerances until the Agency has received data sufficient to perform a tolerance reassessment.

Rationale: Plant and animal metabolism studies, analytical methods, residue studies, storage stability studies, and processing studies are needed before the Agency can determine appropriate tolerance levels and perform a tolerance reassessment. A full set of chronic toxicology data is also required.

7. The Agency is not requiring a reentry interval for metaldehyde products.

Rationale: Based on the toxicological data available to the Agency, metaldehyde products are of low toxicity. Because of these low toxicity levels, it is not considered necessary to establish a reentry interval.

8. The Agency is not requiring protective clothing labeling for end-use products.

Rationale: The available data base for metaldehyde shows that metaldehyde has low acute toxicity. There are no other data to indicate that protective clothing is needed. The Agency will reassess this position when required toxicity studies have been submitted and evaluated.

9. Current label warnings on some products indicating that "Metaldehyde is toxic to fish and wildlife" and "Birds feeding on treated areas may be killed" are not now required.

Rationale: The Agency has no data to support the imposition of such warnings. Available supplementary data indicate that the magnitude of the risk is unlikely to require such warnings for metaldehyde.

10. The Agency will assign priority review for metaldehyde studies involving animal and plant metabolism, potential to contaminate ground water, and exposure to fish and wildlife.

Rationale: The metabolism studies are needed prior to commencement of residue studies and the other studies are needed to determine whether additional studies are required.

11. While data gaps are being filled, currently registered products containing metaldehyde may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Registration Standard. Registrants must provide or agree to develop additional data, as specified in the Data Tables, in order to maintain existing registrations.

Rationale: Even when authorized under FIFRA sections 3(c)(2)(B) and 3(c)(7), the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain this pesticide, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard. To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

Acute Toxicity Limits. The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

Use Patterns. To be registered under this Standard, manufacturing-use products bearing federally registered uses. The EPA Index to Pesticide Chemicals (for availability, see page 1) lists all federally registered uses of this pesticide ingredient, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

All products must bear appropriate labeling as specified in 40 CFR 156.10, PR Notices 83-2, 83-3, and below. Appendix II contains further information on label requirements.

Pesticide products containing this pesticide as an active ingredient may not be released for shipment by the registrant after December 23, 1989, unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Registration Standard.

Pesticide products containing this pesticide as an active ingredient may not be distributed or sold by any person after December 23, 1990, unless that product bears amended labeling that complies with the requirements of this Standard.

The labels of all products must bear the appropriate storage and disposal statements (see Appendix II).

a. Manufacturing-Use Products (MPS)

1. The ingredient statement for MPS must declare the active ingredient as:

> Metaldehyde (2,4,6,8-tetramethyl-1,3,5,7-tetraoxycyclo-octane) . . . . %

2. Labels for MPS must bear the following identifying phrase directly beneath the product name:

> "A molluscicide for formulating use only."

3. In the directions for use, the following statement must appear:

> "Formulators using this product are responsible for obtaining EPA registration of their formulated product."

4. In the directions for use, the following statement regarding acceptable use patterns must appear; however, no use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern:

"For formulation into end-use insecticide products intended only for (list acceptable sites)."

5. If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

6. The following statements are required to appear under the "Environmental Hazards" heading:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

b. End-Use Products (EP)

1. The active ingredient for EPs must declare the active ingredient as:

Metaldehyde (2,4,6,8-tetramethyl-1,3,5,7-tetraoxycyclo-octane) . . . . %

2. All EPs allowing for outdoor uses must bear the following environmental hazards statements:

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

"This pesticide may be fatal to dogs or other pets if eaten. Keep pets out of treated area."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

   1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

   2. The data requirements listed in Tables A and B.[2]

   3. The labeling requirements specified for manufacturing use products in Section IV.

   4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

   1. The data requirements listed in Table A.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption,[3] the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person

who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.

3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing

stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Metalhyde Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

   a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

   a. Application for Pesticide Registration (EPA Form 8570-1).

   b. Two copies of any required product-specific data (See Table B).

   c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

   d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR THE METALDEHYDE TECHNICAL GRADE OF THE ACTIVE INGREDIENT

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation[1]	Must additional data be submitted under FIFRA Section 3(c)(2)(B)?	Time Frame for Data Submission
Part 158 Subpart C - Product Composition					
61-2. Beginning Materials and Production Process	TGAI	No	N/A	Yes[2]	6 months
61-3. Formation of Impurities	TGAI	No	N/A	Yes[3]	6 months
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	No	N/A	Yes[4]	12 months
Physical and Chemical Characteristics					
63-2. Color	TGAI	No	N/A	Yes	6 months
63-3. Physical State	TGAI	No	N/A	Yes	6 months
63-4. Odor	TGAI	No	N/A	Yes	6 months
63-5. Melting Point	TGAI	No	N/A	Yes[5]	6 months
63-6. Boiling Point	TGAI	No	N/A	Yes[6]	6 months
63-7. Density, Bulk Density or Specific Gravity	TGAI	No	N/A	Yes	6 months
63-8. Solubility	TGAI or PAI	No	N/A	Yes	6 months
63-9. Vapor Pressure	TGAI or PAI	No	N/A	Yes	6 months
63-10. Dissociation Constant	TGAI or PAI	No	N/A	Yes	6 months
63-11. Octanol/Water Partitioning Coefficient	PAI	No	N/A	Yes[7]	6 months
63-12. pH	TGAI	No	N/A	Yes[8]	6 months
63-13. Stability	TGAI	No	N/A	Yes	6 months
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

FOOTNOTES

1. Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2. The following information must be provided: (1) the name and address of the producer of the technical grade of the active ingredient; (2) the brand name, trade name or other commercial designation, the name and address of the producer, and information concerning the composition of each starting material; (3) a general characterization of the process (e.g., batch or continuous); (4) a flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, and the duration of each step of the process and of the entire process; (5) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (6) a description of the equipment used; (7) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; (8) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced;

TABLE A.
GENERIC DATA REQUIREMENTS FOR THE METALDEHYDE TECHNICAL GRADE OF THE ACTIVE INGREDIENT

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and (9) a description of the procedures used to assure consistent composition of the substance produced (quality control methods).

3. A discussion regarding the origin of the following potential impurities must be provided: (1) each impurity associated with the active ingredient which was found to be present if any analysis of the product conducted by or for the registrant, and (2) each impurity which the registrant has reason to believe may be present at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur during production, the possible degradation of ingredients after production, post-production reactions between ingredients, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures.

4. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. If the product is produced by a batch process, five separate batches should be represented in preliminary analyses. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided.

5. Data on melting point are required if the technical chemical is a solid at room temperature.

6. Data on boiling point are required if the technical product is a liquid at room temperature.

7. Data on octanol/water partition coefficient are required if the technical chemical is organic and non polar.

8. Data on pH are required if the test substance is dispersible in water.

TABLE A
GENERIC DATA REQUIREMENTS FOR METALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must additional data be submitted?	Time Frame for Data Submission
158.240 Residue Chemistry					
171-4. Qualitative Nature of the residue (Metabolism) - Plants	PAIRA	Partially	00138262.	Yes[1]	18 Months
171-4. Qualitative Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	No	N/A	Yes[2,3]	18 Months
171-4. Residue analytical methods	TGAI and metabolites	Partially	00138262.	Yes[4,5,6]	15 Months
171-4. Storage stability	TEP and metabolites	Partially	00138262.	Yes[7]	18 Months
171-4. Magnitude of the residue in plants8					
Root/Tuber Vegetables Group	TEP	No	N/A	Yes[9] Yes[10,11]	18 Months 24 Months
Leaves of Root/Tuber Vegetables Group Turnip Tops	TEP	No	N/A	Yes[12]	18 Months
Bulb Vegetables Group	TEP	No	N/A	Yes[13]	18 Months
Leafy Vegetables Group	TEP	No	N/A	Yes[14]	18 Months
Brassica Leafy Vegetables Group	TEP	No	N/A	Yes[15]	18 Months
Legume Vegetables Group	TEP	No	N/A	Yes[16]	18 Months
Foliage of Legume Vegetables Group	TEP	No	N/A	Yes[17]	18 Months
Fruiting Vegetables Group	TEP	No	N/A	Yes[18] Yes[19]	18 Months 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must additional data be submitted?	Time Frame for Data Submission
158.240 Residue Chemistry					
Cucurbit Vegetables Group	TEP	No	N/A	Yes[20]	18 Months
Citrus Fruits Group	TEP	No	N/A	Yes[21] Yes[22]	18 Months 24 Months
Pome Fruits Group	TEP	No	N/A	Yes[23] Yes[24]	18 Months 24 Months
Stone Fruits Group	TEP	No	N/A	Yes[25] Yes[26]	18 Months 24 Months
Small Fruits and Berries Group	TEP	Partially	00033213, 00138262	Yes[27] Yes[28]	18 Months 24 Months
Tree Nuts Group	TEP	No	N/A	Yes[29]	18 Months
Cereal Grains Group	TEP	No	N/A	Yes[30] Yes[31,32]	18 Months 24 Months
Grass Forage, Fodder, and Hay Group	TEP	No	N/A	Yes[33]	18 Months
Non-Grass Animal Feeds Group	TEP	Partially	00127145	Yes[34]	18 Months
Herbs and Spices Group	TEP	No	N/A	Yes[35] Yes[36]	18 Months 24 Months
Miscellaneous Commodities					
- Artichoke	TEP	No	N/A	Yes[37]	18 Months
- Asparagus	TEP	No	N/A	Yes[38]	18 Months
- Avocados	TEP	No	N/A	Yes[39]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must additional data be submitted?	Time Frame for Data Submission
- Bananas	TEP	Partially	00127144	Yes[40]	18 Months
- Mint	TEP	No	N/A	Yes[41] Yes[42]	18 Months 24 Months
- Okra	TEP	No	N/A	Yes[43]	18 Months
- Tobacco	PAIRA & TEP	No	N/A	Yes[44] Yes[45]	18 Months 18 Months
171-4. Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	No	N/A	Reserved[46]	18 Months

1. Data depicting the distribution and metabolism of universally ring-labeled [^{14}C]metaldehyde in or on three dissimilar food crops (e.g., a root crop, a legume or cereal grain crop, and a leafy vegetable) are required. If metabolism is not similar in the three crops, additional studies using other crops may be required. A completely characterized test substance representative of technical metaldehyde used in commercial formulations must be applied foliarly and via the soil several times up to and including the day of harvest at rates sufficiently high to permit complete characterization of ^{14}C-residues. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate terminal residues. Representative samples must also be analyzed by proposed enforcement methods to ascertain that all residues of concern are determined.

2. Metabolism studies utilizing ruminants and poultry are required. Animals must be dosed orally for a minimum of 3 days with universally ring-labeled [^{14}C]metaldehyde at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using enforcement methods to ascertain that the methods are capable of adequately recovering and identifying all residues of toxicological concern.

3. Data depicting the qualitative nature of metaldehyde residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of metaldehyde in these animals differs from that in rats.

4. The results of a successful confirmatory trial of the Selim and Seiber GLC method (or other proposed enforcement method) conducted by an independent laboratory must be submitted for a representative fatty and nonfatty plant-derived food commodity. The rationale for selection of commodities must be provided. If the method must be significantly modified to accommodate analysis of specific commodities, separate confirmatory trials for each specific commodity are required. Results of at least one set of samples per commodity (a total of six samples, including two control samples, two control samples fortified at the tolerance level, and two control samples fortified at 2-5 times the tolerance level) must be submitted. No more than three sets of samples per commodity may be tested to achieve successful recovery rates of 70-120% with negligible interference compared tot he established tolerance(s). For additional details of data requirements, refer to PR Notice 88-5, Tolerance Enforcement Methods - Independent Laboratory Confirmation by Petitioner.

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5. The nature of the residue in plants and animals has not been adequately described. If the metabolism studies requested in the section "Qualitative Nature of the Residue in Plants" reveal the presence of additional metabolites of concern in or on plant commodities, additional validated methods for data collection and tolerance enforcement will be required. Also, if the metabolism studies requested in the section "Qualitative Nature of Residue in Animals" reveal the presence of residues of concern in meat, milk, or eggs, validated methods for data collection and tolerance enforcement will be required.

6. Representative samples of fatty and nonfatty plant commodities bearing residues of metaldehyde must be subjected to multiresidue protocols I and III which are available from the National Technical Information Service under Order No. PB203735/AS. If residues of concern are found in animal commodities, these commodities must also be subjected to analysis using multiresidue protocols I and III.

7. All residue data requested in this Standard must accompanied by information specifying the storage intervals and conditions for samples analyzed. Data must also be provided which depict the decline in metaldehyde residues of concern in commodities stored under the range of conditions and for the range of intervals specified. One representative sample from each crop group bearing field-weathered residues or fortified samples must be analyzed immediately after harvest or fortification and again after storage intervals that represent actual residue sample storage conditions and allow for reasonable unforeseen delays in sample analysis. For additional guidance on conducting storage stability studies, the Registrant is referred to an August 1987 "Position Document on the Effects of Storage on Validity of Pesticide Residue Data" available from NTIS under order no. PB88112362/AS.

8. It should be noted that data gaps exist for plant and animal metabolism and storage stability. Since the data required for individual commodities are dependent on the metabolism data, that the required metabolism data must be obtained and submitted for review prior to initiation of residue trials.

9. Data are required depicting metaldehyde residue of concern in or on (1) carrots, radishes, and potatoes harvested after the last multiple soil applications with a pelleted/tableted (p/t) formulation at 20 lb ai/A as a broadcast soil treatment repeated at 14-day intervals and (2) sugar beets harvested 6 days following the last of multiple broadcast soil applications (7-day intervals) with the 4% P/T formulation at 2.4 lb ai/A. Radish, carrot, and potato samples must be collected immediately after the last application and at several closely spaced intervals thereafter so that a residue uptake and decline curve can be established. Tests for carrots, potatoes, and radishes must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce). Sugar beet tests must be conducted in OR.

10. Data depicting residues of concern in granules, chips, wet peel, and dry peel processed from potatoes bearing measurable weathered residue must be submitted. If residues concentrate, appropriate food/feed additive regulations must be proposed.

11. Data depicting metaldehyde residues of concern in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable weathered residue must be submitted. If residues concentrate, appropriate food/feed additive regulations must be proposed.

12. Data are required depicting metaldehyde residues of concern in or on (i) turnip tops harvested following the last of multiple applications with a P/T formulation at 20 lb ai/A applied as a broadcast soil application at 14-day intervals and (ii) sugar beet tops harvested 6 days following the last of multiple broadcast soil applications (7 day intervals) with the 4% P/T formulation at 2.4 lb ai/A. Turnip top samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests on turnips must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce. Tests on sugar beets tops must be conducted in OR.

13. Data are required depicting metaldehyde residue of concern in or on onions (green and dry bulb) and garlic following the last of several soil treatments with a P/T formulation at 20 lb ai/A applied as a broadcast soil treatment using ground equipment repeated at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Test must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural

Statistics, (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

14. Data are required depicting metaldehyde residue of concern in or on celery, lettuce (head and leaf) and spinach following the last of several applications with a P/T formulation at 20 lb ai/A made as a broadcast soil treatment using ground equipment and repeated at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

15. Data are required depicting metaldehyde residue of concern in or on broccoli, cabbage and mustard greens following the last of several broadcast soil applications with a P/T formulation at 20 lb ai/A repeated at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

16. Data are required depicting metaldehyde residue of concern in or on beans and peas (a succulent and dry variety of each) following the last of several soil applications made at 14-day intervals with a P/T formulation at 20 lb ai/A. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

17. Data are required depicting metaldehyde residue of concern in or on bean vines and hay and pea vines and hay harvested following the last of multiple soil treatments with a P/T formulation at 20 lb ai/A applied as a broadcast soil treatment repeated at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce)

18. Data are required depicting metaldehyde residue of concern in or on peppers and tomatoes harvested following the last of multiple broadcast soil treatments with a P/T formulation at 20 lb ai/A. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

19. Data are required depicting metaldehyde residues of concern in dry pomace, puree, catsup, and juice processed from tomatoes bearing measurable, weathered residues. If residues concentrate in any product, an appropriate food/feed additive regulation must be proposed.

20. Data are required depicting metaldehyde residue of concern in or on cucumbers, melons (cantaloupe or muskmelon), and summer squash following the last of several broadcast soil application with a P/T formulation at 20 lb ai/A applied at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

21. Data are required depicting metaldehyde residue of concern in or on grapefruits, lemons, and oranges following the last of several broadcast soil applications with a P/T formulation at 1.5 lb ai/A. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

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22. Data are required depicting metaldehyde residues of concern in wet and dried pulp, oil molasses, and juice processed from citrus bearing measurable, weathered residues. If residue concentrate in any product, an appropriate food/feed additive regulation must be proposed.

23. Data are required depicting metaldehyde residue of concern in or on apples and pears following the last of several broadcast soil applications with a P/T formulation at 1.5 lb ai/A. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

24. Data depicting metaldehyde residues of concern in juice, and wet and dry pomace processed from apples bearing measurable, weathered residues are required. If residue concentrate in any product, an appropriate food/feed additive regulation must be proposed.

25. Data are required depicting metaldehyde residue of concern in or on cherries (sweet and sour), plums, and peaches following the last of several broadcast soil treatments with a P/t formulation at 1.5 lb ai/A. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

26. Data are required depicting metaldehyde residues of concern in dried prunes processes from plums bearing measurable weathered residues. If residues concentrate in dried prunes, an appropriated food additive regulation must be proposed.

27. Data are required depicting metaldehyde residue of concern in or on (i) blackberries and grapes harvested after the last of multiple broadcast soil applications with the 2.75% P/T made at 7-day intervals at 1.5 lb ai/A, (ii) blueberries harvested after the last or multiple broadcast soil application with the 10% G made at 7-day intervals at 1.6 lb ai/A , (iii) strawberries harvested 6 days after the last of multiple applications at 14-day intervals with a G formulation at 5.23 lb ai/A, and (iv) strawberries harvested after the last of multiple soil-directed applications at 21-day intervals with the 3.25% EC formulation at 1.12 lb ai/A (4 gal product/A). Samples of blackberries, grapes, blueberries, and strawberries (iv only) must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

28. A processing study depicting metaldehyde residues of concern in products (raisins, dry pomace, raisin waste, and juice) processed from grapes bearing measurable, weathered residues is required. If residues concentrate in any product, appropriate food/feed additive regulations must be proposed.

29. Data depicting metaldehyde residue of concern in or on almonds, pecans and walnuts harvested following the last of multiple broadcast soil treatments with the 2% G MAI formulation at 0.44 lb ai/A applied at 14-day intervals using ground equipment. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

30. Data depicting metaldehyde residues of concern in or on (i) wheat grain harvested 30 days after the last of several broadcast soil applications of a G formulation at 2.4 lb ai/A, (ii) wheat grain harvested after the last of several broadcast soil applications with a G formulation at 2.4 lb ai/A, (ii) wheat grain harvested after the last of several broadcast soil applications with a G formulation at 1.5 lb ai/A [wheat grown for seed], and (iii) corn grain (field corn) and sweet corn kernels plus cob with husks removed harvested after the last of several broadcast soil applications made at 14-day intervals with a P/T formulation at 20 lb ai/A. Samples of wheat grown for seed (ii) and corn must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states

that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture U.S. Dept. of Commerce).

31. A processing study is required depicting metaldehyde residues of concern in wet milled products (starch, crude oil, and refined oil) and in dry milled products (grits, meal, flour, crude and refined oils), and grain dust from the processing of field corn bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive.regulations must be proposed.

32. A processing study depicting metaldehyde residues of concern in milled products (bran, flour, middling and shorts) and grain dust from the processing of wheat bearing measurable, weathered residues is required. If residues concentrate in any product, appropriate food/feed additive regulations must be proposed. [Wheat data will be translated to oats and barley].

33. Data are required depicting metaldehyde residues of concern in or on grass hay, forage and seed (Bermuda grass, bluegrass, and bromegrass or fescue) harvested after the last of several broadcast soil application with a G formulation made at 7-day intervals at 1.5 lb ai/A. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Dept. of Commerce).

34. Data are required depicting metaldehyde residue of concern in or on alfalfa and clover hay, forage, and seed harvested after the last of multiple soil applications with the 4% G formulation at 2.4 lb ai/A applied as broadcast soil applications and repeated at 7-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter such that a residue uptake and decline curve can be established. Test must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce).

35. Data are required depicting metaldehyde residue of concern in or on coriander (seeds and foliage), chives, dill (seeds and foliage), oregano, and sage harvested 6 days following the last of multiple soil treatments with the 4% G formulation at 2.4 lb ai/A applied as a broadcast treatment prior to the formation of edible parts, and as a band application following edible part formation, at 7-day intervals using ground equipment. Tests must be conducted in states that represent the major growing regions for each crop according to the latest edition of Agricultural statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce).

36. Data are required depicting metaldehyde residues of concern in or on dried herbs and spices. If residues concentrate in any herb or spice, an appropriate food additive regulation must be proposed.

37. Data are required depicting metaldehyde residue of concern in or on artichokes harvested following the last of multiple broadcast soil treatments with a P/T formulation at 20 lb ai/A and repeated at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter so that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for artichokes according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce).

38. Data are required depicting metaldehyde residue of concern in or on asparagus harvested following the last of multiple broadcast soil treatments with a P/T formulation at 20 lb ai/A and repeated at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter so that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for artichokes according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce).

39. Data are required depicting metaldehyde residue of concern in or on avocados harvested following the last of multiple broadcast soil treatments with

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a P/T formulation at 1.5 lb ai/A using ground equipment. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter so that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for avocados according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce).

40. Data are required depicting metaldehyde residue of concern in or on bananas harvested following the last of multiple broadcast soil treatments with the 10% G formulation at 4.8 lb ai/A and repeated at 14-day intervals using ground equipment. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter so that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for bananas according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce).

41. Data are required depicting metaldehyde residue of concern in or on spearmint or peppermint harvested 30 days following the last of multiple broadcast soil treatments with the 4% P/T formulation at 2.4 lb ai/A, repeated at 7-day intervals. Tests must be conducted in OR.

42. Data are required depicting metaldehyde residues of concern in or on spend hay and oil processed from fresh mint bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive regulation must be proposed.

43. Data are required depicting metaldehyde residue of concern in or on okra harvested following the last of multiple broadcast soil treatments with a P/T formulation at 20 lb ai/A using ground equipment applied at 14-day intervals. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter so that a residue uptake and decline curve can be established. Tests must be conducted in states that represent the major growing regions for okra according to the latest edition of Agricultural Statistics (USDA) or the 1982 Census of Agriculture (U.S. Department of Commerce).

44. Data are required depicting metaldehyde residue of concern in or on green and cured or dry tobacco harvested following the last of multiple broadcast soil treatments with the 3.25% P/T formulation at 1.4 lb ai/A using ground equipment. Samples must be collected immediately after the last application and at several closely spaced intervals thereafter so that a residue uptake and decline curve can be established.

45. If metaldehyde residues of concern are $\geq$ 0.1 ppm in or on dry or cured tobacco, pyrolysis products derived from the active ingredient must be characterized and the level of the residue in smoke must be quantified. Universally ring-labeled $[^{14}C]$ metaldehyde must be used for identification of pyrolysis products.

46. Data requirements regarding the magnitude of the residue in animal products will not be determined until all requested data regarding metabolism in animals and magnitude of residue in feed items have been received.

Table A
Generic Data Requirements for Metaldehyde

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Submission
Section 158.290 Environmental Fate						
DEGRADATION STUDIES - LAB:						
161-1 - Hydrolysis		A,B,E,F,H,I	No		Yes	9 months
PHOTODEGRADATION						
161-2 - In Water		A,B	No		Yes	9 months
161-3 - On Soil		A	No		Yes	9 months
161-4 - In Air		A	No		Reserved[1]	
METABOLISM STUDIES - LAB:						
162-1 - Aerobic Soil		A,B,E,F,H	No		Yes	27 months
162-2 - Anaerobic Soil		A	No		Yes	27 months
162-3 - Anaerobic Aquatic		-	No		No[2]	
162-4 - Aerobic Aquatic		-	No		No[2]	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption		A,B,E,F,H	No		Yes	12 months
163-2 - Volatility (Lab)		A,E,F	No		Yes	9 months

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Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data[1]/ Submission
Section 158.290 Environmental Fate (cont'd)						
163-3 - Volatility (Field)		A,E,F	No		Reserved/1	
DISSIPATION STUDIES - FIELD:						
164-1 - Soil		A,B,H	No		Yes	27 Months
164-2 - Aquatic (Sediment)		-	No		No[2]	
164-3 - Forestry		-	No		No[3]	
164-4 - Combination and Tank Mixes		-	No		No[4]	
164-5 - Soil, Long-Term		A	No		Reserved/5	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)		A	No		Yes	39 Months
165-2 - Rotational Crops (Field)		A	No		Reserved/6	
165-3 - Irrigated Crops		-	No		No[2]	
165-4 - In Fish		A,B,D	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms		A,B,D	No		Reserved/7	

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Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
40 CFR 158.390						
Reentry Protection:						
132-1 - Foliar Dissipation	TEP	A,B,E,F,H,I	No		Reserved[1]	
132-1 - Soil Dissipation	TEP	A,B,E,F	No		Reserved[1]	
133-3 - Dermal Exposure	TEP	A,B,C,D,E,F,G,H,I	No		Reserved[1]	
133-4 - Inhalation Exposure	TEP	A,B,C,D,E,F,G,H,I	No		Reserved[1]	
Section 158.440 Spray Drift						
202-1 - Spray Field Evaluation		A,B	No		Reserved[8]/	
202-1 - Drift Size Spectrum		A,B	No		Reserved[8]/	
Ground Water Monitoring		B,C,E,F,H	No		No[9]	

FOOTNOTES

1/ This data requirement is reserved pending evaluation of the laboratory volatility data.

2/ Data are not required because there are no aquatic or aquatic impact uses.

3/ Based on use pattern, study is not required.

4/ Currently not imposed.

5/ This data requirement is reserved pending evaluation of the aerobic soil metabolism, leaching, and dissipation data.

6/ Pending evaluation of the confined crop rotation data and/or toxicological data.

7/ This data requirement is deferred pending the evaluation of the fish accumulation study and ecological issues.

8/ Spray drift data requirements are deferred pending evaluation of ecological effect issues.

9/ There are no data at present time to trigger ground water monitoring studies.

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Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.340 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral - Rat	TGAI	A,B,E,F,H,I	Partially	00131435, 00131969	Yes[1]	9 Months
81-2 - Acute Dermal	TGAI	A,B,E,F,H,I	Partially	00131434	Yes[1]	9 Months
81-3 - Acute Inhalation - Rat	TGAI	A,B,E,F,H,I	Partially	00131429	Yes[1]	9 Months
81-4 - Eye Irritation - Rabbit	TGAI	A,B,E,F,H,I	No		Yes	9 Months
81-5 - Dermal Irritation- Rabbit	TGAI	A,B,E,F,H,I	Partially	00131971	Yes[1]	9 Months
81-6 - Dermal Sensitization Guinea Pig	TGAI	A,B,E,F,H,I	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	N/A	No		No[2]	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding -						
Rodent	TGAI	A,B,E,F,H,I	No		No[3]	
Nonrodent	TGAI	A,B,E,F,H,I	No		No[3]	

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Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.340 Toxicology						
SUBCHRONIC TESTING (cont'd):						
82-2 - 21-Day Dermal	TGAI	A,B,E,F,H,I	No		Yes	9 Months
82-3 - 90-Day Dermal	TGAI	A,B,E,F,H,I	No		No[4]	
82-4 - 90-Day Inhalation	TGAI	A,B,E,F,H,I	No		No[5]	
82-5 - 90-Day Neurotoxicity	TGAI	N/A	No		No[6]	
CHRONIC TESTING:						
83-1 - Chronic Testing						
-Rodent	TGAI	A,B,E,F,H,I	No		Yes	50 Months
-Nonrodent	TGAI	A,B,E,F,H,I	No		Yes	50 Months
83-2 - Oncogenicity Study						
-Rat	TGAI	A,B,E,F,H,I	No		Yes	50 Months
-Mouse	TGAI	A,B,E,F,H,I	No		Yes	
83-3 -Teratogenicity						
-Rat	TGAI	A,B,E,F,H,I	No		Yes	15 Months
-Mouse	TGAI	A,B,E,F,H,I	No		Yes	15 Months

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Generic Data Requirements for Metaldehyde

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.340 Toxicology						
CHRONIC TESTING (cont'd):						
83-4 - Reproduction	TGAI	A,B,E,F,H,I	No		Yes	39 Months
MUTAGENICITY TESTING:						
84-2 - Gene Mutation	TGAI	A,B,E,F,H,I	No		Yes	9 Months
84-2 - Chromosome Aberration	TGAI	A,B,E,F,H,I	Partially	00163832	Yes?	"
84-4 - Other Mechanisms of Mutagenicity	TGAI	A,B,E,F,H,I	No		Yes	"
SPECIAL TESTING:						
85-1 - General Metabolism	PAI or PAIRA		No		Yes	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METALDEHYDE

FOOTNOTES (Cont.)

1/ This requirement may be satisfied if the purity of the test material used in the existing study is submitted.

2/ This test is required only for compounds which are organophosphate inhibitors of cholinesterase, or related to such inhibitors or metabolites of such inhibitors. Metaldehyde is not an organophosphate; therefore, a study is not required.

3/ Data requirement waived based on the requirement for a chronic oral toxicity study in rodent and nonrodent.

4/ This study is not required because existing acceptable use patterns should not result in repeated or extended human skin contact.

5/ This study is not required because existing acceptable use patterns should not result in repeated or extended human contact by the inhalation route.

6/ Since an acute neurotoxicity study is not required for this compound and there is no evidence of neurotoxicity in mammalian species from the available data, this study is not required.

7/ The portion of the study performed in the absence of a metabolic activation system is acceptable and need not be repeated. However, the portion of the study performed in the presence of the metabolic activation system is not acceptable because neither cytotoxicity not the limit of solubility was demonstrated.

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Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.490 - Wildlife and Aquatic Organisms						
SPECIAL TESTING						
70-1 - Residue Monitoring	TEP	A,B,H	No		Reserved[1/]	
AVIAN AND MAMMALIAN TESTING						
71-1 -Avian Acute Oral Toxicity	TGAI	A,B,F,H	No		Yes	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird	TGAI	A,B,F,H	No		Yes	9 Months
- Waterfowl	TGAI	A,B,F,H	No		Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,B,F,H	No		No[2]	
71-4 - Avian Reproduction						
- Upland Game Bird	TGAI	A,B,F,H	No		Yes	24 Months
- Waterfowl	TGAI	A,B,F,H	No		Yes	24 Months
71-5 - Simulated Field Testing						
- Mammals	TEP	A,B,H	No		Reserved[1/]	
- Birds	TEP	A,B,H	No		Reserved[1/]	
- Actual Field Testing						
- Mammals	TEP	A,B,H	No		Reserved[1/]	
- Birds	TEP	A,B,H	No		Reserved[1/]	

Table A
Generic Data Requirements for Metaldehyde

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.490 - Wildlife and Aquatic Organisms						
AQUATIC ORGANISM TESTING						
72-1 - Acute Toxicity to Freshwater Fish Species						
- Coldwater	TGAI	A,B,F,H	No		Yes	9 Months
- Warmwater	TGAI	A,B,F,H	Yes	0090362	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,F,H	No		Yes	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A,B,F,H	No		Reserved[1/]	
- Mollusk	TGAI	A,B,F,H	No		Reserved[1/]	
- Shrimp	TGAI	A,B,F,H	No		Reserved[1/]	
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle						
- Freshwater Species	TGAI	A,B,H	No		Reserved[1/]	
- Estuarine/Marine	TGAI	A,B,H	No		Reserved[1/]	
72-5 - Fish Life Cycle	TGAI	A,B,H	No		Reserved[1/]	

Table A
Generic Data Requirements for Metaldehyde

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Require- ment? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.490 - Wildlife and Aquatic Organisms						
72-6 - Aquatic Organisms	TEP	A,B,H	No		No[3]	
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A,B,H	No		Reserved[1]	
- Actual Field Testing - Aquatic Organisms	TEP	A,B,H	No		Reserved[1]	

1/ Data requirement reserved pending results of avian/aquatic organism toxicity and environmental fate studies.
2/ Based on use patterns, this study is not required.
3/ See environmental fate data tables (Section 158.290, Guideline 165.50).

Table A
Generic Data Requirements for Metaldehyde

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.540 - Plant Protection						
121-1 - Target Area Phytotoxicity	EP	A,B,F,H	No		No[1]/	
Tier I						
Nontarget Area Phytotoxicity						
121-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,F,H	No		No[1]/	
122-1 - Vegetative Vigor	TGAI	A,B,F,H	No		No[1]/	
122-2 - Aquatic Plant Growth	TGAI	A,B,F,H	No		No[1]/	
Tier II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,F,H	No		No[1]/	
123-1 - Vegetative Vigor	TGAI	A,B,F,H	No		No[1]/	
123-2 - Aquatic Plant Growth	TGAI	A,B,F,H	No		No[1]/	
Tier III						
124-1 Terrestrial Field	TEP	A,B,F,H	No		No[1]/	
124-2 - Aquatic Field	TEP	A,B,F,H	No		No[1]/	

1/ Based on available data, these studies are not required.

Table A
Generic Data Requirements for Metaldehyde

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.590 - Nontarget Insects						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Toxicity	TGAI	A,B,H	No		No[1]	
141-2 - Honey Bee - Toxicity of residues on foliage	TEP	A,B	No		No[1]	
141-4 - Honey Bee Subacute Feeding Study	Reserved2/					
141-5 - Field Testing for Pollinators	TEP	A,B,H	No		No[1]	
Nontarget Insect Testing						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[2]/					
142-2 - Aquatic Insect Life Cycle Study	Reserved[2]/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[2]/					
143-1 thru 143-3 Nontarget Insect Testing-Predators and Parasites	Reserved[2]/					

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[1]/ The nature of the registered metaldehyde formulations and uses precluded any significant bee exposure. Thus, bee data are not required for metaldehyde.

[2]/ This requirement is reserved pending development of test methodology and/or decisions as to whether data should be required.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING METALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation 1	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
Part 158, Subpart C - Product Chemistry					
Product Composition					
61-1. Product Composition	MP	No	N/A	Yes[2]	6 Months
61-2. Beginning Materials and Production or Formulation Process	MP	No	N/A	Yes[3]	6 Months
61-3. Formation of Impurities	MP	No	N/A	Yes[4]	6 Months
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	No	N/A	Yes[5]	12 Months
62-2. Certified Limits	MP	No	N/A	Yes[6]	12 Months
62-3. Enforcement Analytical Methods	MP	No	N/A	Yes[7]	12 Months
Physical and Chemical Characteristics					
63-2. Color	MP	No	N/A	Yes[8]	6 Months
63-3. Physical State	MP	No	N/A	Yes[8]	6 Months
63-4. Odor	MP	No	N/A	Yes[8]	6 Months
63-7. Density, Bulk Density, Specific Gravity	MP	No	N/A	Yes[8]	6 Months
63-12. pH	MP	No	N/A	Yes[8,9]	6 Months
62-14. Oxidizing or Reducing Action	MP	No	N/A	Yes[10]	6 Months
62-15. Flammability	MP	No	N/A	Yes[11]	6 Months
63-16. Explodability	MP	No	N/A	Yes[12]	6 Months
63-17. Storage Stability	MP	No	N/A	Yes	6 Months
63-18. Viscosity	MP	No	N/A	Yes[13]	15 Months
63-19. Miscibility	MP	No	N/A	Yes[14]	6 Months
63-20. Corrosion Characteristics	MP	No	N/A	Yes	15 Months
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING METALDEHYDE

1. Not Applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2. For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, the following information must be provided: (1) the CA-approved chemical name, CAS Registry Number, any common names, the nominal concentration, upper and lower certified limits in accordance with 40 CFR Section 158.175, and the purpose of each active and inert ingredient in the product; (2) the molecular, structural and empirical formulae, and the molecular weight or weight range of each active ingredient in the product; (3) the chemical name and nominal concentration of each impurity of toxicological significance associated with the active ingredient or present in any sample at a level equal to or greater than 0.1% by weight of the TGAI; and (4) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that are not characterized. Impurities must be identified as such. For each manufacturing-use product that is produced from an EPA_registered product, the following information must be provided: (1) the chemical and common name of each active ingredient as listed on the source product, its nominal concentration in the product based upon the nominal concentration in the source product, and upper and lower certified limits i accordance with 158.175; (2) the CA-approved chemical name of each inert ingredient in the product, its CAS Registry Number, any common names, nominal concentration, purpose, and upper and lower certified limits in accordance with 158.175; and (2) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that cannot be characterized.

3. For each manufacturing-end use product that is produced from an EPA-registered product, the following information must be provided: (1) the name and EPA-registered product; (2) the brand name, trade name, or other commercial designation and information concerning the composition of each inert ingredient; (3) a general characterization of the formulation or production process (e.g., batch or continuous); (4) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (5) a description of the equipment used; (6) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; and (7) a description of the procedures used to assure consistent composition of the substance produced (quality control methods). For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, the following information must be provided in addition to that listed above: (1) the name and address of the producer of each starting material, the name and address of its producer, and information concerning its composition; (3) a flow chart of the chemical equations of each intended reaction occurring at each step of the process and of the entire process; and (4) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

4. For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, a discussion regarding the origin of the following potential impurities must be provided: (1) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (2) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. For each manufacturing use product that is produced from an EPA-registered product, a discussion must be provided for each impurity associated with the active ingredient which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w.w) based on the possible carryover of impurities present in the registered product which serves as the source of the active ingredient, the possible carryover of impurities present in the inert ingredients in the product, possible reactions occurring during the formulation of the product, post-production reactions between any of the product's active ingredients and any other component of the product or its packaging, and possible contamination from packaging materials or production equipment.

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TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING METALDEHYDE

5. For each manufacturing use product produced by an integrated system, the registrant must provide preliminary analyses of five or more representative samples of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1% or greater of the TGAI. If the product is produced by a batch process, at least five separate batches should be represented. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted, along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted.

6. The registrant must propose upper and lower limits for each active and inert ingredient, if such limits would differ from the standard certified limits determined by the Agency according to 40 CFR Section158.175(b)(2). Also, if the manufacturing use product contains the technical grade of the active ingredient only or is produced by an integrated system, upper limits must be proposed for each toxicologically significant impurity associated with the active ingredients and found to be present in any sample of the product (standard certified limits cannot be used for impurities). Certified limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production. The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85).

7. Analytical methods which are suitable for enforcement purposes must be provided for each active ingredient and each additional ingredient or impurity that is determined to be toxicologically significant. Suitability for enforcement purposes shall be determined from validation studies of method accuracy and precision submitted by the registrant.

8. As required in 40 CFR Section 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability explodability, storage stability, viscosity, miscibility, and corrosion characteristics).

9. Data on pH are required if the test substance is dispersable in water.

10. Data are required on oxidizing/reducing potential if product contains an oxidizing or reducing agent.

11. Data are required on flammability if the product contains combustible liquids.

12. Data are required if the product is potentially explosive.

13. Data on viscosity are required if the product is a liquid.

14. Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Metaldehyde

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Section 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP	All	No		Yes	9 Months
81-2 - Acute Dermal	MP	All	No		Yes	9 Months
81-3 - Acute Inhalation - Rat	MP	All	No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	MP	All	No		Yes	9 Months
81-5 - Dermal Irritation -Rabbit	MP	All	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	No		Yes	9 Months

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.56(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of Part 152, Subpart I. You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";
(B) "Among the least toxic chemicals known"
(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ****" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use*. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978; amended at 53 FR 15952, May 4, 1988]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Metaldehyde Standard

MRID Citation

00033213 Leganer, R.R.; Getzin, L.W.; Kimura, Y.; et al. (1962) Pesticide Residue Analysis. (Unpublished study received Mar 9, 1964 under 271-12; prepared by Washington State Univ., Dept. of Agricultural Chemistry, submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:001932-B)

00090362 McCann, J.A. (1972) [Metaldehyde 99%: Bluegill (Lepomis macro chirus)]: Test No. 454. (U.S. Agricultural Research Serv- ice, Pesticides Regulation Div., Animal Biology Laboratory, Fish Toxicity Laboratory; unpublished study; CDL:130286-A)

00127144 Morgareidge, K. (1964) Analysis of Bananas for Residues of Metaldehyde: Laboratory No. 85214 a-g, 85352 a-f, 85385 a-f. (Unpublished study received May 9, 1964 under unknown admin. no.; prepared by Food and Drug Research Laboratories, Inc., submitted by United Fruit Co., Boston, MA; CDL:119840-A)

00127145 Jones, L. (1956) Determination of Metaldehyde Spray Residue: R.D.M.-6804. (Unpublished study received Mar 19, 1957 under 271-12; submitted by International Minerals & Chemical Corp., Terre Haute, IN; CDL:119896-A)

00131429 Berczy, Z.; Cobb, L.; Cherry, C. (1973) Acute Inhalation Toxicity to the Rat of Metaldehyde Dust: LZA1/73891. (Unpublished study received Aug 19, 1983 under 6836-90; prepared by Huntingdon Research Centre, Eng., submitted by Lonza, Inc., Fair Lawn, NJ; CDL:251377-A)

00131434 Davies, R.; Collins, C. (1974) Acute Percutaneous Toxicity to Rats of Metaldehyde: Report No. 2330/D3/74. (Unpublished study received Aug 19, 1983 under 6836-90; prepared by Huntingdon Research Centre, Eng., submitted by Lonza, Inc., Fair Lawn, NJ; CDL:251377-F)

00131435 Hackenberg, U. (1973) Acute Toxicity of Metaldehyde after Administration of a Single Intragastric Dose to Female Rats: A 0409/1061.2. (Unpublished study received Aug 19, 1983 under 6836-90; prepared by Institute fur Biologische Forschung GmbH, submitted by Lonza, Inc., Fair Lawn, NJ; CDL:251377-G)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Metaldehyde Standard

MRID Citation

00131969 Hackenberg, U. (1973) Acute Toxicity of Metaldehyde after a Single Intragastric Dose in the Male Rat: Report A 0409/1061.1; Inbifo Code No. S 2221 A. (Unpublished study received Sep 6, 1983 under 6836-90; prepared by Inbifo Institut fur Biologische Forschung, W. Ger., submitted by Lonza, Inc., Fair Lawn, NJ; CDL:251378-A)

00131971 Jones, J.; Hoare, A. (1983) P0071: A Primary Skin Irritation and Corrosivity Study in the Rabbit: Report No. 3478-733/165. (Unpublished study received Sep 6, 1983 under 6836-90; prepared by Hazleton Laboratories Europe, Ltd., Eng., submitted by Lonza, Inc., Fair Lawn, NJ; CDL:251380-A)

00138262 Interregional Research Project No. 4 (1974) The Results of Tests on the Amount of Metaldehyde Residue Remaining in or on Strawberries Including a Description of the Analytical Methods Used. (Compilation; unpublished study received Jun 19, 1974 under 4E1519; CDL:072538-A)

00163832 Debets, F. (1986) Evaluation of the Ability of P0071 To Induce Chromosome Aberrations in Cultured Chinese Hamster Ovary (CHO) Cells: NOTOX 0227/EC 112. Unpublished study prepared by NOTOX V.O.F. 23 p.

IV. FORM APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO**
PRODUCT NAME	
APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________________
Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _________ concerning a requirement for submission of "generic" data on the active ingredient ________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ___________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _________ and their registration number(s) is/are __________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: ____________________ ______________________________
(Typed)

EPA Form 8570-3

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date____________________

Guidance Document for____________________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No.______________________ Date______________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

*(To qualify, certify **ALL** four items)*

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

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